Hazardous Waste Pharmaceuticals & Amendment to the Nicotine (P075) Listing

Delaware Department of Natural Resources and Environmental Control
Division of Waste and Hazardous Substances
Compliance and Permitting Section
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DELAWARE DEPARTMENT OF
NATURAL RESOURCES AND
ENVIRONMENTAL CONTROL

Background

- Historically, hazardous waste pharmaceuticals were fully regulated as hazardous wastes and required healthcare facilities to send all hazardous waste pharmaceuticals to a permitted hazardous waste treatment, storage, or disposal facility.
- Hazardous waste regulations were difficult to apply to the healthcare industry.
- EPA and Delaware had previously allowed unwanted pharmaceuticals to be sent for reverse distribution with the presumption the pharmaceuticals would be used, reused, or reclaimed and the reverse distributor was not acting as a waste management service.

Background

- EPA determined that in almost all cases, hazardous waste pharmaceuticals were being disposed by the reverse distributor (i.e., there was no use or reuse). As such, the hazardous waste pharmaceuticals were a waste at the individual healthcare facility because there was no legitimate expectation they would be used or reused by the reverse distributor.

- Because of this, EPA and state inspectors identified numerous potential violations at healthcare facilities.

- Key take-away: Healthcare facilities have always been subject to hazardous waste regulation. This rule is simply tailoring regulations to the healthcare industry.

Acronyms

- RCRA – Resource Conservation and Recovery Act
- EPA – Environmental Protection Agency
- DEA – Drug Enforcement Administration
- FDA – Food and Drug Administration
- LQG – Large Quantity Generator
- SQG – Small Quantity Generator
- VSQG – Very Small Quantity Generator
- TSDF – Treatment, Storage, or Disposal Facility
- OTC – Over-the-Counter
- NRT – Nicotine Replacement Therapy
- POTW – Publicly Owned Treatment Works (wastewater treatment plant)

Goals of the Final Rule

- Provide regulations that are tailored to the healthcare industry
- Eliminate intentional sewering of hazardous waste pharmaceuticals
- Eliminate dual regulation of hazardous waste pharmaceuticals by EPA/DEA/FDA and associated state agencies
- Clarify how RCRA applies to reverse logistics and reverse distribution
- Re-evaluate the regulation of over-the-counter nicotine replacement therapies (OTC NRTs)

Who is Subject to the Rule?

Facilities that generate waste OTC NRTs carrying the P075 waste code

Healthcare facilities that generate hazardous waste pharmaceuticals

Reverse Distributors

Who is Not Subject to the Rule?

- Households (EPA and DNREC continue to recommend household hazardous waste pharmaceuticals are taken to a collection event for disposal)
- Farmers, ranchers, and fisheries that may administer pharmaceuticals to their animals
- RCRA-permitted treatment, storage, and/or disposal facilities (TSDFs)
- Non-healthcare facilities that generate or otherwise manage hazardous waste pharmaceuticals

Amendment of the P075 Nicotine Listing
§261.33

- FDA-approved over-the-counter nicotine replacement therapies (OTC NRT) are no longer included in the P075 listing
- Patches, gums, and lozenges no longer meet the criteria for acute hazardous waste
- FDA-approved OTC nicotine patches, gums, and lozenges can be discarded as non-hazardous solid waste

≠ P075

DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL

Amendment of the P075 Nicotine Listing

§261.33

- Nicotine continues to be a listed, acute hazardous waste (P075)
- Other unused formulations of nicotine are still considered P075 when discarded
  - E-liquids/e-juices in e-cigarettes, cartridges, or vials
  - Prescription nicotine (e.g., nasal spray, inhaler)
  - Legacy pesticides containing nicotine
  - Nicotine used in research and manufacturing

= P075

DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL

Reverse Distribution vs. Reverse Logistics

- EPA addressed the final part of its Retail Strategy in the Pharmaceutical Rule

- Preamble language specifically provides guidance on reverse logistics
  - Differentiates reverse distribution and reverse logistics
  - Guidance on reverse logistics applies to all retail goods, not just pharmaceuticals

Reverse Distribution vs. Reverse Logistics

Reverse Distribution	Reverse Logistics
Prescription pharmaceuticals	Non-prescription pharmaceuticals • e.g., over-the-counter pharmaceuticals and dietary supplements All other unsold retail items
No redistribution occurs	Redistribution occurs via: • Donation • Liquidation (secondary market)
Items are solid waste at the healthcare facility	Items are not a solid waste IF there is a reasonable expectation of legitimate use/reuse or reclamation
Addressed in Part 266, Subpart P	Newly codified in Part 266, Subpart P, but affirms EPA's existing policy

Hazardous Waste Pharmaceutical Rule

- EPA concluded that prescription pharmaceuticals sent to reverse distributors to determine manufacturer credit are solid wastes at the healthcare facility (i.e., there is no expectation of legitimate reuse or reclamation)

- As such, EPA created a new set of regulations to address the management of hazardous waste pharmaceuticals

- New regulatory provisions are found in DRGHW Part 266, Subpart P

Definitions: Healthcare Facility

Means any person that is lawfully authorized to:

(1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.

Definitions: Healthcare Facility

Includes, but is not limited to:

- Wholesale distributors
- Third-party logistics providers that serve as forward distributors
- Military medical logistics facilities
- Hospitals
- Psychiatric hospitals
- Ambulatory surgical centers
- Health clinics
- Physicians' offices
- Optical and dental providers

Definitions: Healthcare Facility

Also includes, but is not limited to:

- Chiropractors
- Long-term care facilities
- Ambulance services
- Pharmacies
- Long-term care pharmacies
- Mail-order pharmacies
- Retailers of pharmaceuticals
- Veterinary clinics
- Veterinary hospitals
- Vape shops

Definitions: Healthcare Facility

Does NOT include:

- Pharmaceutical manufacturers
- Reverse distributors
- Reverse logistics centers

Definitions: Pharmaceutical

- Any drug or dietary supplement for use by humans or other animals
- Any electronic nicotine delivery system (*e.g.*, electronic cigarette or vaping pen)
- Any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (*e.g.*, pre-filled cartridges or vials).




Definitions: Pharmaceutical

Includes, but is not limited to:

- Dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act
- Prescription drugs, as defined by 21 CFR 203.3(y)
- Over-the-counter drugs
- Homeopathic drugs
- Compounded drugs
- Investigational new drugs
- Pharmaceuticals remaining in non-empty containers

Definitions: Pharmaceutical

Includes, but is not limited to:

- Personal protective equipment contaminated with pharmaceuticals
- Clean-up material from spills of pharmaceuticals
- Electronic nicotine delivery systems (e.g., e-cigarettes, vaping pens)
- Nicotine e-liquid/e-juice packaged for retail sale in use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials)

Definitions: Pharmaceutical

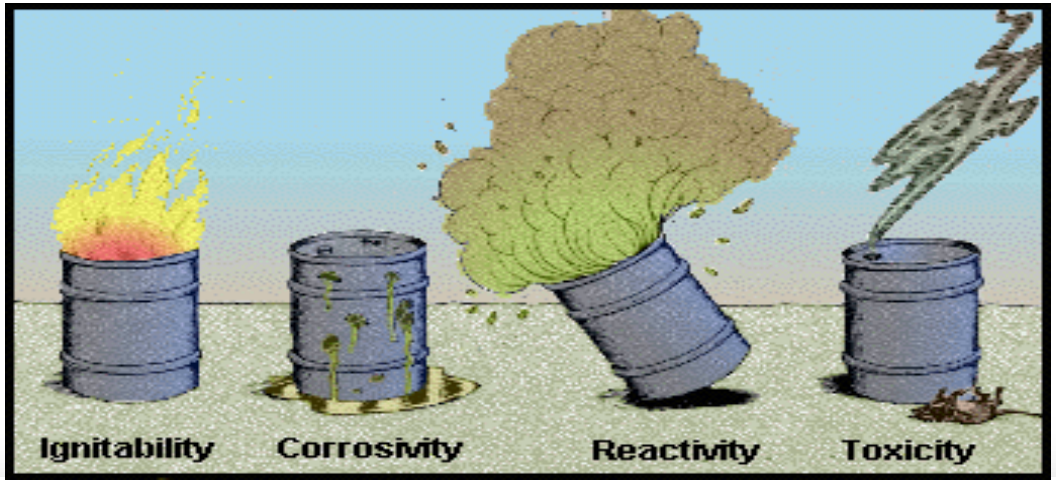
Does NOT include:

- Dental amalgam
- Sharps
- Infectious waste
- Bulk nicotine e-liquids

Definitions: Hazardous Waste Pharmaceutical

A pharmaceutical that is a solid waste AND

- Exhibits one or more characteristics of hazardous waste OR
- Is a listed hazardous waste



Definitions: Hazardous Waste Pharmaceutical

A pharmaceutical is NOT a solid waste (and therefore not a hazardous waste pharmaceutical) if it is legitimately used, reused, or reclaimed.

Definitions: Hazardous Waste Pharmaceutical

Three types of hazardous waste pharmaceuticals

- Potentially-creditable
- Non-creditable
- Evaluated

Definitions: Potentially-Creditable Hazardous Waste Pharmaceutical

A prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is:

- (1) In original manufacturer packaging (except pharmaceuticals that were subject to a recall);
- (2) Undispensed; and
- (3) Unexpired or less than one year past expiration date.

Definitions: Potentially-Creditable Hazardous Waste Pharmaceutical

Does not include:

- Evaluated hazardous waste pharmaceuticals
- Nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.
  - Examples: electronic nicotine delivery systems, over-the-counter pain medications, cold medicines, etc.

Definitions: Non-Creditable Hazardous Waste Pharmaceutical

- A prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit through reverse distribution

OR

- A nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed through reverse logistics

Definitions: Non-Creditable Hazardous Waste Pharmaceutical

Includes but is not limited to:

- Investigational drugs
- Free samples of pharmaceuticals received by healthcare facilities
- Residues of pharmaceuticals remaining in empty containers
- Contaminated personal protective equipment
- Floor sweepings
- Clean-up material from the spills of pharmaceuticals

Definitions: Evaluated Hazardous Waste Pharmaceutical

A prescription hazardous waste pharmaceutical that:

- Has been evaluated by a reverse distributor in accordance with Part 266, Subpart P

AND

- Will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit

Summary: Hazardous Waste Pharmaceutical

Potentially-Creditable	Non-Creditable	Evaluated
Prescription pharmaceutical with reasonable expectation of manufacturer credit • In original packaging • Undispensed • Unexpired or less than 1 year after expiration date	• Prescription pharmaceutical without a reasonable expectation of manufacturer credit • Nonprescription pharmaceutical without a reasonable expectation to be legitimately used/reused or reclaimed	• Prescription pharmaceutical that has been evaluated for manufacturer credit and does not need further evaluation

Definitions: Non-Hazardous Waste Pharmaceutical

A pharmaceutical that is a solid waste, but does NOT

- Exhibit one or more characteristics of hazardous waste and
- Is not a listed hazardous waste

Definitions: Non-Pharmaceutical Hazardous Waste

A hazardous waste that is listed or characteristic but does not meet the definition of a pharmaceutical.

Definitions: Long Term Care Facility

A licensed entity that provides assistance with activities associated with daily living, including managing and administering pharmaceuticals to one or more individuals at the facility

Includes:

- Hospice facilities
- Nursing facilities
- Skilled nursing facilities
- Nursing and skilled nursing care portions of continuing care retirement communities.

Does NOT include:

- Group homes
- Independent living communities
- Assisted living facilities
- Independent and assisted living portions of continuing care retirement communities

Definitions: Reverse Distributor

- Any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit.

- Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit

When Is a Healthcare Facility Subject to Part 266, Subpart P?

Counting all hazardous waste, including hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste, does the healthcare facility generate > 1 kg of acute HW/month or > 100 kg of non-acute HW/month?

NO

Healthcare facility is NOT subject to Subpart P, except as noted below. Healthcare facility is a VSQG regulated under Part 262 for all of its hazardous waste, including hazardous waste pharmaceuticals and non-pharmaceutical waste.

YES

Is the hazardous waste generated considered a pharmaceutical?

NO

Healthcare facility manages its non-pharmaceutical waste under Part 262 as a VSQG, SQG, or LQG. Only non-pharmaceutical waste is counted toward monthly generator category.

YES

Healthcare facility manages its hazardous waste pharmaceuticals under Part 266, Subpart P. Hazardous waste pharmaceuticals are NOT counted toward monthly generator category.

Note: All VSQGs are subject to the sewer prohibition of §266.505 and the empty container standards of §266.507, and can use the optional provisions of §266.504.

What is Not Subject?

- Pharmaceuticals that are not a solid waste because they are legitimately used/reused (e.g., lawfully donated for their intended purpose) or reclaimed
- Investigational new drugs for which an investigational new drug application is in effect in accordance with FDA regulations (rule applies after FDA approves destruction)
- Hazardous waste pharmaceuticals that are also controlled substances regulated by the DEA

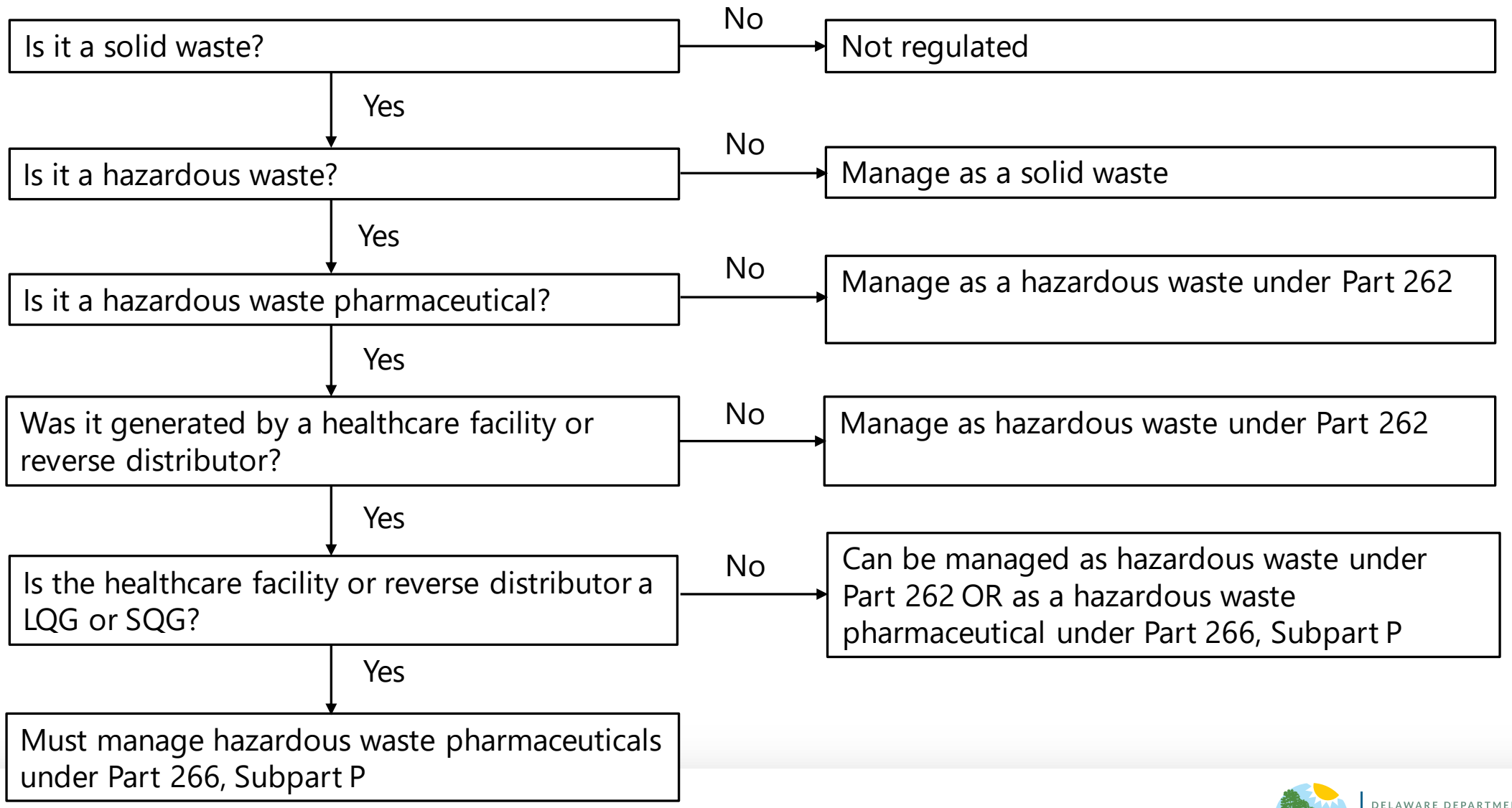
What is Not Subject?

- Pharmaceuticals being managed in accordance with a recall strategy approved by the FDA (but ARE SUBJECT after the FDA approves destruction)
- Pharmaceuticals being managed in accordance with a recall corrective action plan that has been approved by the Consumer Product Safety Commission (but ARE SUBJECT after the CPSC approves destruction)
- Pharmaceuticals stored according to a preservation order or during an investigation or judicial proceeding until the proceedings have concluded and/or the decision to discard is made

What is Not Subject?

- Non-hazardous waste pharmaceuticals
  - Healthcare facility has option to manage non-hazardous waste pharmaceuticals under Subpart P to avoid having to make HW determinations on all waste pharmaceuticals (remember, pharmaceuticals don't count toward generator status!)
  - If healthcare facility segregates hazardous waste pharmaceuticals from non-hazardous waste pharmaceuticals, EPA recommends following best management practices identified in "Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States"

Overview of the HW Pharm. Rule



Overview of Part 266 Subpart P

- Subpart P is only applicable to the hazardous waste pharmaceuticals generated at healthcare facilities or reverse distributors
  - Does not apply to pharmaceuticals at non-healthcare facilities
  - Have option of also managing non-hazardous waste pharmaceuticals under Subpart P
- Management of other solid wastes, hazardous wastes, universal wastes, or infectious wastes must be in compliance will all other applicable regulations

Overview of Part 266 Subpart P

- What does Subpart P cover?
  - Mandatory management of hazardous waste pharmaceuticals by LQG or SQG healthcare facilities and reverse distributors
  - Optional management of hazardous waste pharmaceuticals by VSQG healthcare facilities (otherwise, manage under Part 262)
  - Optional management of non-hazardous waste pharmaceuticals by any generator
  - Sewering ban on hazardous waste pharmaceuticals
  - Management of controlled substances regulated by DEA

How Do I Know if My Facility is Required to Comply with Subpart P?

- Determine amount of acute and non-acute hazardous waste generated prior to the implementation of Subpart P (i.e., the total amount of non-pharmaceutical hazardous waste PLUS the amount of hazardous waste pharmaceuticals)

+

= TOTAL

Determining Generator Status

- If total amount of non-pharmaceutical hazardous waste and hazardous waste pharmaceuticals is:

≤1kg acute AND <100 kg non-acute	≤1kg acute AND Between 100 and 1,000 kg non-acute	>1kg acute OR >1,000 kg non-acute
⬇	⬇	⬇
VSQG	SQG	LQG

Determining Applicability of Part 266 Subpart P

- LQGs and SQGs – Must comply with Subpart P (cannot opt to manage hazardous waste pharmaceuticals under Part 262)

- VSQGs – Subject to Part 262 and 3 provisions in Subpart P (can optionally choose to comply with Subpart P; however, if they choose to comply with Subpart P, must comply with all provisions)

Three Types of Hazardous Waste Pharmaceuticals

Healthcare Facility

1st Reverse Distributor

2. Potentially-Creditable

1. Non-creditable

3. Evaluated

2. Potentially-Creditable

3. Evaluated

HW TSD

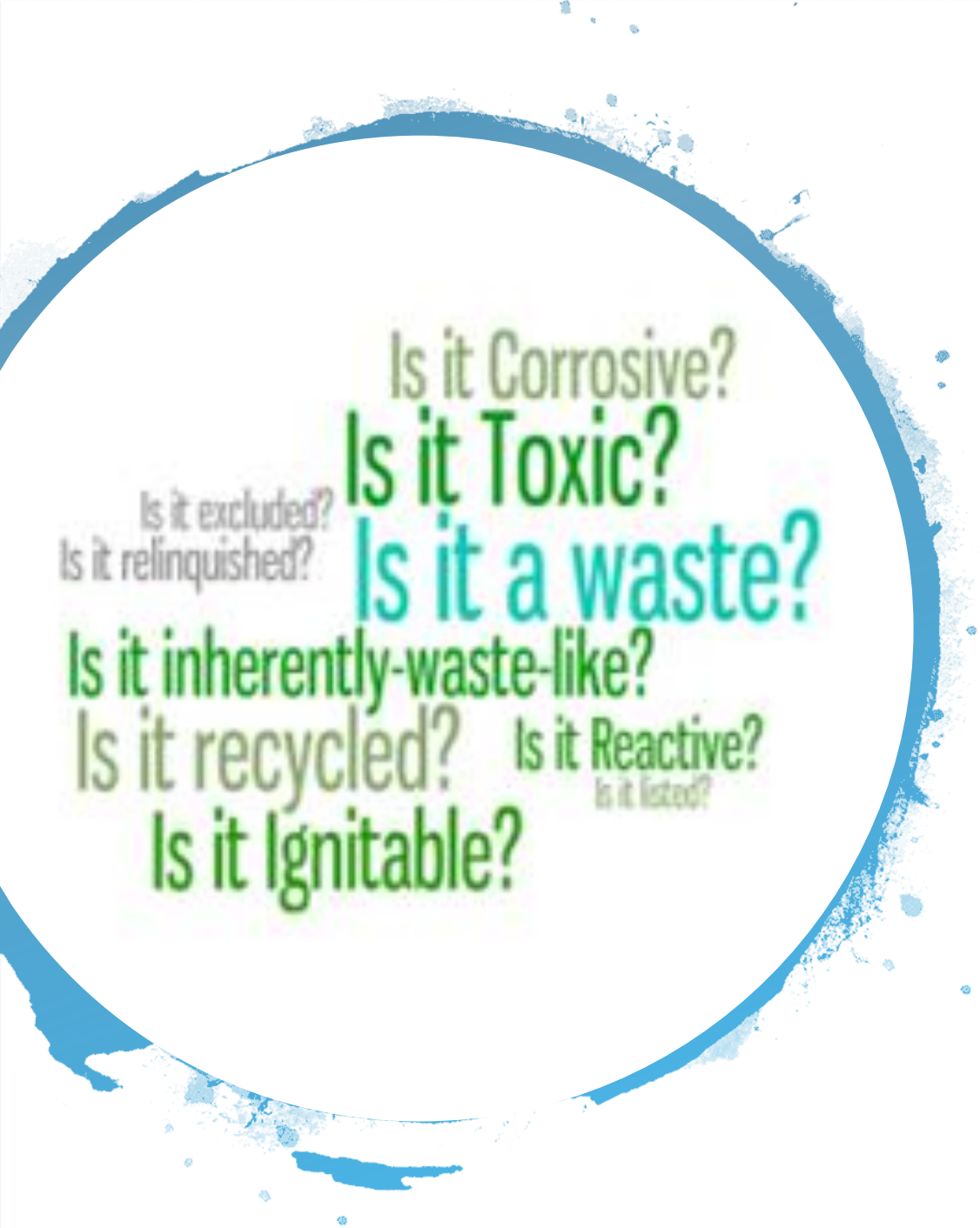
2nd Reverse Distributor

Managing Non-Creditable Hazardous Waste Pharmaceuticals

§266.502

Non-creditable hazardous waste pharmaceuticals includes but is not limited to:

- Investigational drugs
- Free samples of pharmaceuticals received by healthcare facilities
- Residues of pharmaceuticals remaining in empty containers
- Contaminated personal protective equipment
- Floor sweepings
- Clean-up material from the spills of pharmaceuticals



Managing Non-Creditable Hazardous Waste Pharmaceuticals §266.502

- Hazardous waste determination
  - Must determine if the non-creditable hazardous waste pharmaceuticals are hazardous waste
  - Can elect to manage non-hazardous waste pharmaceuticals as hazardous waste pharmaceuticals under Subpart P and avoid having to make the determination
  - However, if healthcare facility elects to manage all waste pharmaceuticals as hazardous waste pharmaceuticals, it must comply with all requirements in Subpart P for that waste

Managing Non-Creditable Hazardous Waste Pharmaceuticals

§266.502

- Notification
  - Healthcare facility must notify that it is operating under Subpart P
  - If healthcare facility is subject to annual reporting requirements, notification can be submitted with the next annual report (Site ID Form) – annual reporting cycle has already concluded in Delaware
  - If healthcare facility is not subject to annual reporting requirements, notification is due within 60 days of the effective date of the regulations (which was March 22, 2021) or within 60 days of the date the healthcare facility became subject to Subpart P (Form 8700-12) – **DNREC is extending compliance deadline to July 31, 2021.**
  - Copy of the notification form must be kept at the healthcare facility as long as the healthcare facility is subject to Subpart P

Managing Non-Creditable Hazardous Waste Pharmaceuticals
§266.502

- Notification - Withdraw
  - Healthcare facility that is no longer subject to Subpart P because it is a VSQG and elects to withdraw from Subpart P must notify that it is no longer operating under Subpart P before operating under the VSQG generator requirements in Part 262
  - Notification to withdraw from Subpart P must be maintained at the healthcare facility for 3 years from the date of signature on the notification of withdrawal

Managing Non-Creditable Hazardous Waste Pharmaceuticals
§266.502

- Notification
  - Notification forms can be submitted online through myRCRAid or using the paper version of Form 8700-12
  - https://dnrec.alpha.delaware.gov/waste-hazardous/management/hazardous/reporting/

Managing Non-Creditable Hazardous Waste Pharmaceuticals
§266.502

- Training
  - Healthcare facility must ensure all personnel are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal operations and emergencies
  - This is not an annual requirement
  - Note: If healthcare facility is a LQG for non-pharmaceutical hazardous waste, it must also comply with the LQG training requirements for employees handling those hazardous wastes – which is an annual requirement

Managing Non-Creditable Hazardous Waste Pharmaceuticals
§266.502

- Container Standards
  - Container must be structurally sound, compatible with contents, and lacking evidence of leakage, spillage, or damage that could cause leakage or spillage
  - If hazardous waste pharmaceutical is ignitable or reactive or healthcare facility commingles incompatible hazardous waste pharmaceuticals, container must be managed so it does not have the potential to:
    - Generate extreme heat, pressure, fire, explosion, or violent reaction
    - Produce uncontrolled toxic or flammable fumes
    - Damage the structural integrity of the container
    - Threaten human health or the environment

Managing Non-Creditable Hazardous Waste Pharmaceuticals
§266.502

- Container Standards
  - Container must be kept closed and secured in a manner to prevent unauthorized access
  - Non-hazardous waste pharmaceuticals and hazardous waste pharmaceuticals can be placed in the same container; however, hazardous waste pharmaceuticals prohibited from being combusted must be accumulated in a separate container and labeled with all applicable hazardous waste codes
    - Part 268 Appendix XI for full list – includes mercury (U151), selenium sulfide (U205) and arsenic trioxide (P012)

Managing Non-Creditable Hazardous Waste Pharmaceuticals
§266.502

- Labeling
  - Containers must be clearly marked with the words "Hazardous Waste Pharmaceuticals"
  - Containers of hazardous waste pharmaceuticals prohibited from being combusted must also be labeled with hazardous waste codes

Managing Non-Creditable Hazardous Waste Pharmaceuticals
§266.502

- Accumulation Time
  - Healthcare facilities can accumulate hazardous waste pharmaceuticals for up to one year without a permit or interim status
  - Accumulation time can be demonstrated by:
    - Marking or labeling container with accumulation start date
    - Maintaining an inventory system that identifies the date a hazardous waste pharmaceutical first became a waste
    - Placing the hazardous waste pharmaceutical in a specific area and identifying the earliest date than any of the hazardous waste pharmaceuticals in the area became a waste

Managing Non-Creditable Hazardous Waste Pharmaceuticals §266.502

- Response to Spills
  - Immediately contain all spills
  - Manage spill clean-up materials as non-creditable hazardous waste pharmaceuticals

Managing Non-Creditable Hazardous Waste Pharmaceuticals
§266.502

- Land Disposal Restriction (LDR) Requirements
  - Must comply with LDR requirements in Part 268, with the exception of identifying Hazardous Waste Codes on LDR Notification (can use PHARMS or PHRM code)
  - Exception: Hazardous Waste Codes must be identified for those hazardous waste pharmaceuticals that are prohibited from being combusted

Shipping Non-Creditable Hazardous Waste Pharmaceuticals §266.508

- Package and label in accordance with DOT regulations
- Ship waste to a designated facility (TSDF) on a hazardous waste manifest using a permitted hazardous waste transporter
  - Instead of hazardous waste codes, write "PHARMS" in Item 13 (EPA guidance also allows "PHRM")
  - Note: hazardous waste codes are required for those hazardous waste pharmaceuticals that are prohibited to be combusted
- Exports subject to Part 262, Subpart H

Managing Non-Creditable Hazardous Waste Pharmaceuticals
§266.502

- Rejected Loads
  - Healthcare facility can accumulate rejected/returned hazardous waste pharmaceuticals for 90 days upon receipt of the rejected load
  - Upon receipt, healthcare facility must:
    - Sign Item 18c on the original manifest if the original manifest was used to return the shipment
    - Sign item 20 on the new manifest if a new manifest was used to return the shipment
    - Within 30 days of receipt of returned shipment, send a copy of the manifest back to the designated facility that returned the shipment
    - Within 90 days, ensure waste is transported off-site in accordance with 266.508(a)

Managing Non-Creditable Hazardous Waste Pharmaceuticals
§266.502

- Reporting Requirements
  - Annual report in NOT required under Subpart P (though an annual report may be required if the healthcare facility is a LQG for non-pharmaceutical hazardous wastes
  - Exception Reporting
    - If healthcare facility does not receive a signed copy of a manifest back from the designated facility within 60 days, the healthcare facility must submit a legible copy of the manifest and note with the manifest stating the return copy was not received with a description of efforts taken to locate the hazardous waste pharmaceuticals to DNREC
  - Additional reports can be requested by the Secretary relating to the quantity and disposition of hazardous waste pharmaceuticals

Managing Non-Creditable Hazardous Waste Pharmaceuticals

§266.502

- Recordkeeping Requirements
  - Manifests must be retained for 3 years
  - Exception reports must be retained for 3 years from date of report
  - Hazardous waste determination documentation – 3 years from date waste last sent to TSD (no documentation required if all waste pharmaceuticals are managed as hazardous waste pharmaceuticals)
  - Training records for 3 years
  - Records must be readily available upon request by a DNREC inspector (can be paper or electronic copies)
  - Record retention periods automatically extend during unresolved enforcement action or as requested by DNREC

Managing Non-Creditable Hazardous Waste Pharmaceuticals

§266.502

- Acceptance of hazardous waste pharmaceuticals from off-site
  - Hazardous waste pharmaceuticals can be accepted from an off-site healthcare facility that is a VSQG provided:
    - The receiving healthcare facility and the VSQG healthcare facility are under the control of the same person as defined in §260.10.
    - The receiving healthcare facility is operating under Subpart P
    - The receiving healthcare facility manages all received hazardous waste pharmaceuticals under Subpart P
    - The receiving healthcare facility keeps records of the shipments it receives from off-site

Managing Non-Creditable Hazardous Waste Pharmaceuticals

§266.502

- Acceptance of hazardous waste pharmaceuticals from off-site (continued)
  - A manifest is not required – a record of the shipment is required to be maintained, but there are no specific requirements related to the type of record required

Managing Potentially-Creditable Hazardous Waste Pharmaceuticals

§266.503

- Prescription pharmaceuticals that have a reasonable expectation that manufacturer credit will be issued
  - Must be in original packaging (unless subject to recall)
  - Must be undispensed
  - Must be unexpired or less than 1 year after expiration date

DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL

Managing Potentially-Creditable Hazardous Waste Pharmaceuticals

§266.503

- Potentially-creditable hazardous waste pharmaceuticals are those that are sent to a reverse distributor to be evaluated
- Healthcare facility must make hazardous waste determinations (if managing all non-hazardous waste pharmaceuticals as hazardous waste pharmaceuticals, the determination is not required)
- Healthcare facility is prohibited from sending non-pharmaceutical hazardous waste to the reverse distributor

Managing Potentially-Creditable Hazardous Waste Pharmaceuticals
§266.503

- No container labeling requirements
- No container standards
- No accumulation limits

Managing Potentially-Creditable Hazardous Waste Pharmaceuticals

§266.503

- Reporting
  - Annual report is NOT required under Subpart P (though an annual report may be required if the healthcare facility is a LQG for non-pharmaceutical hazardous wastes
- Recordkeeping (3 years)
  - Copy of shipping paper used to send potentially-creditable hazardous waste pharmaceuticals to a reverse distributor
  - Documentation confirming delivery to a reverse distributor
  - Records must be readily available upon request by a DNREC inspector

Managing Potentially-Creditable Hazardous Waste Pharmaceuticals §266.503

- Response to Spills
  - Immediately contain all spills
  - Manage spill clean-up materials as non-creditable hazardous waste pharmaceuticals

Managing Potentially-Creditable Hazardous Waste Pharmaceuticals
§266.503

- Acceptance of hazardous waste pharmaceuticals from off-site
  - Hazardous waste pharmaceuticals can be accepted from an off-site healthcare facility that is a VSQG provided:
    - The receiving healthcare facility and the VSQG healthcare facility are under the control of the same person
    - The receiving healthcare facility is operating under Subpart P
    - The receiving healthcare facility manages all received hazardous waste pharmaceuticals under Subpart P
    - The receiving healthcare facility keeps records of the shipments it receives from off-site

Shipping Potentially-Creditable Hazardous Waste Pharmaceuticals §266.500

- Comply with DOT shipping requirements
- A hazardous waste manifest is NOT required
- Common carrier is acceptable (e.g., USPS, UPS, FedEx)
- If delivery confirmation is not received within 35 calendar days of shipment date, healthcare facility must contact the carrier and reverse distributor to report and determine the status
- Exports are subject to Part 262, Subpart H

Healthcare Facility Standards

	Non-Creditable HW Pharms	Potentially-Creditable HW Pharms
Labeling	✓	None
Container Standards	✓	None
Maximum Accumulation Time	✓	None
Hazardous Waste Determinations*	✓	✓
Over-managing non-hazardous waste pharmaceuticals & commingling with non-hazardous waste pharmaceuticals	Allowed	Allowed
Manifest	✓	None
Include hazardous waste pharmaceuticals in annual report	No	No

* Not required for either type if managing all pharmaceutical waste as hazardous

VSQGs – What Are the Options?
§266.504

- Continue managing hazardous waste pharmaceuticals under Part 262
  - Label "Hazardous Waste" or "Waste" with a description of contents
  - Accumulate up to 1,000 kg of hazardous waste or 1 kg of acute hazardous waste*
  - Ship on hazardous waste manifest
- Fully opt in to Subpart P and comply with all provisions (and manage non-pharmaceutical hazardous waste under Part 262)

* Accumulating waste in excess of these limits subjects the site to more stringent standards

VSQGs – What Are the Options?
§266.504

- Use the optional provisions in Subpart P
  - Send potentially-creditable hazardous waste pharmaceuticals to a reverse distributor
  - Send hazardous waste pharmaceuticals (non-creditable and potentially-creditable) to another facility under the same ownership
    - Receiving facility must be operating under Subpart P, or
    - VSQG can send hazardous waste to LQG in accordance with §262.14(a)(6)(viii)
  - VSQG can send its hazardous waste pharmaceuticals to a facility with which the VSQG has a contractual agreement as a supplier of pharmaceuticals

Long-Term Care Facilities
§266.504

- A long-term care facility that is a VSQG may dispose of its hazardous waste pharmaceuticals (excluding contaminated PPE or clean-up materials) in a DEA-authorized/approved on-site collection receptacle provided the contents are managed in accordance with DEA requirements for controlled substances
- A long-term care facility with 20 beds or fewer is presumed to be a VSQG
- A long-term care facility with more than 20 beds that operates as a VSQG must demonstrate that it generates quantities of hazardous waste that are within the VSQG limits

Sewering Ban
§266.505

- All entities are prohibited from disposing of hazardous waste pharmaceuticals down the drain.

- Note: Controlled substances are not regulated under Subpart P
  - Controlled substance disposal is subject to DEA's non-retrievable standard
  - Sewering does not meet the non-retrievable standard
  - Exception: Pharmaceutical wastage (i.e., pharmaceuticals that have already been dispensed to a patient) are not subject to the non-retrievable standard and if non-hazardous can be sewered. Pharmaceuticals in the pharmacy inventory requiring disposal must meet non-retrievable standard

Residues of Hazardous Waste Pharmaceuticals in Empty Containers

§266.507

- Previously, residues of acute hazardous waste pharmaceuticals were regulated as acute hazardous waste unless the container was triple-rinsed and the rinse water managed as acute hazardous waste.

- This rule provides clarifications for what is considered to be an empty container (and thus not regulated as hazardous waste).

Residues of Hazardous Waste Pharmaceuticals in Empty Containers

§266.507

- The following containers are considered empty and not regulated as hazardous waste:
  - A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills) provided the pharmaceuticals have been removed from the container using commonly employed practices to remove materials
  - A unit-dose container (e.g., a unit-dose cup, wrapper, blister pack, or delivery device) provided the pharmaceuticals have been removed from the container using commonly employed practices to remove materials

Residues of Hazardous Waste Pharmaceuticals in Empty Containers

§266.507

- The following containers are considered empty and not regulated as hazardous waste (continued):
  - A syringe provided the contents have been removed by fully depressing the plunger of the syringe
  - An intravenous (IV) bag provided the contents have been fully administered to a patient

- If a syringe or IV bag is not empty, the syringe or IV bag (with its remaining contents) must be placed in a container that is managed and disposed of as non-creditable hazardous waste pharmaceuticals

Residues of Hazardous Waste Pharmaceuticals in Empty Containers

§266.507

- Hazardous waste pharmaceuticals remaining in any other type of unused, partially administered, or fully administered container must be managed as non-creditable hazardous waste pharmaceuticals, unless the container held non-acute hazardous waste pharmaceuticals and is empty (defined in §261.7(b)(1) or (2))
  - This includes, but is not limited to residues in:
    - Inhalers
    - Aerosol cans
    - Nebulizers
    - Tubes of ointments, gels, or creams
    - Electronic nicotine delivery systems (e.g., e-cigarette or vaping pen)

Residues of Hazardous Waste Pharmaceuticals in Empty Containers

§266.507

	Non-acute HW Pharms	Acute HW Pharms*
Stock/Dispensing Bottles (1 liter or 10,000 pills) and Unit-Dose Containers	Remove contents	Remove contents
Syringes	Fully depress plunger	Fully depress plunger
IV Bags	Fully administer contents or §261.7(b)(1)	Fully administer contents
Other Containers	§261.7(b)(1) or (2) "RCRA empty"	Can not be RCRA empty (manage as non-creditable hazardous waste pharmaceutical)

* No triple rinsing of containers with acute hazardous waste pharmaceuticals

Controlled Substances

§266.506

- Controlled substances are those drugs regulated by the DEA. Their purchase, storage, and use are strictly monitored. They are divided into five schedules based on potential for abuse:
  - Schedule I includes drugs that have no accepted medical use, such as heroin
  - Schedule II drugs are used medically, but have the highest potential for abuse (e.g., morphine)
  - Schedule III through V are drugs with decreasing abuse potential (e.g., cough suppressants and sedatives)
- Hazardous waste pharmaceuticals that are also controlled substances are only regulated by the DEA (provided conditions of exemption are met)

Controlled Substances

§266.506

- There are only 8 hazardous waste pharmaceuticals that are also controlled substances:
  - Chloral; chloral hydrate
  - Fentanyl sublingual spray
  - Phenobarbital
  - Testosterone gels
  - Valium injectables
  - Paraldehyde – no longer commonly used
  - Paregoric – no longer commonly used
  - Opium tincture – no longer commonly used

Controlled Substances
§266.506

- Conditional exemption applies to:
  - Hazardous waste pharmaceuticals that are on a controlled substance list in 21 CFR Part 1308 (list is on previous slide)
  - Household hazardous waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector registered with the DEA that commingles household hazardous waste pharmaceuticals with controlled substances from an ultimate user

- Note: authorized collector and ultimate user are defined by DEA

Controlled Substances
§266.506

- Conditions for exemption:
  - Comply with the sewering prohibition
  - Collect, store, transport, and dispose of hazardous waste pharmaceuticals in compliance with all applicable DEA regulations for controlled substances
  - Destroy the hazardous waste pharmaceuticals in a method that the DEA has publicly deemed in writing to meet the non-retrievable standard or in an acceptable combustion unit

Controlled Substances

§266.506

- Acceptable units for the combustion of hazardous waste pharmaceuticals
  - Permitted large municipal waste combustor
  - Permitted small municipal waste combustor
  - Permitted hospital, medical, and infectious waste combustor
  - Permitted commercial and industrial solid waste incinerator
  - Permitted hazardous waste combustor

Controlled Substances
§266.506

- Pharmaceutical wastage
  - Controlled substances that have been dispensed to a patient, but have not been fully administered are not subject to DEA's non-retrievable standard and thus can be sewered; however, hazardous waste pharmaceuticals that are also controlled substances are still subject to the sewering ban under EPA's rules.
  - Therefore, the 8 medications listed earlier cannot be be sewered under any circumstances

Controlled Substances

§266.506

- 8 hazardous waste pharmaceuticals that are also controlled substances and thus cannot be sewered under any circumstance:
  - Chloral; chloral hydrate
  - Fentanyl sublingual spray
  - Phenobarbital
  - Testosterone gels
  - Valium injectables
  - Paraldehyde – no longer commonly used
  - Paregoric – no longer commonly used
  - Opium tincture – no longer commonly used

Controlled Substances

§266.506

- Sequestration devices alone cannot be used to manage hazardous waste pharmaceuticals that are also controlled substances – does not meet the exclusion in §266.506, as DEA has not publicly deemed in writing that the technology meets its non-retrievable standard
- If sequestration devices are used, the device must be combusted afterward to meet the exclusion.

- Note: it appears that sequestration devices may be used for pharmaceutical "wastage," as the non-retrievable standard is not applicable to pharmaceutical "wastage." Check with DEA/Office of Controlled Substances for more information.

FAQs

- EPA has a wide-ranging set of frequently asked questions on their webpage:

https://www.epa.gov/hwgenerators/frequent-questions-about-management-standards-hazardous-waste-pharmaceuticals-and

FAQs

- Can a healthcare facility operating under Subpart P send potentially-creditable hazardous waste pharmaceuticals to a reverse distributor in a state that has not yet adopted Subpart P?

Yes. The healthcare facility is required to comply with Subpart P. While the reverse distributor is not required to comply with Subpart P, as a practical matter, it would need to comply with portions of Subpart P to ensure the healthcare facility can maintain compliance, including providing delivery confirmation to the healthcare facility. However, this burden is expected to be minimal, as this can be achieved by the reverse distributor signing for a shipment delivered by common carrier.

FAQs

- Can a healthcare facility consolidate hazardous waste pharmaceuticals at a healthcare facility owned by the same entity in another state?

Yes. There is no limitation on where the receiving healthcare facility must be located.

FAQs

- Are intermediate care facilities (ICF) considered healthcare facilities?

No, intermediate care facilities (described in 42 CFR 440.150(a)) are not considered healthcare facilities subject to Subpart P. EPA has determined ICFs have more in common with group homes or assisted living facilities than long-term care facilities with skilled nursing.

FAQs

- Do e-cigarettes qualify for the nicotine P075 hazardous waste listing amendment?

No, all forms of nicotine-containing e-cigarettes, e-liquids, electronic nicotine delivery systems, etc. are still considered hazardous waste with the waste code P075 when discarded. However, they can potentially be managed as pharmaceuticals under Subpart P.

FAQs

- E-liquids pre-packaged for retail sale are considered hazardous waste pharmaceuticals. How are other e-liquids, such as house blends, regulated?

According to the FDA, any entity that makes, modifies, mixes, manufactures, fabricates, assembles, processes, labels, repacks, relabels, or imports any tobacco product is a tobacco product manufacturer. E-liquids used by tobacco product manufacturers are not included in the definition of hazardous waste pharmaceuticals and thus are fully regulated under DRGHW Part 262 as P075 hazardous waste.

*Note: Nicotine (P075) is an acute hazardous waste. Any residue remaining in a container that held nicotine is also fully regulated as P075 waste.

FAQs

- How does this rule impact vape shops that are VSQGs?
  - Pre-packaged e-liquids can be returned to a reverse logistics center provided there is a reasonable expectation they will be used/re-used or reclaimed. These would not be considered solid wastes or hazardous wastes
  - If cannot be returned to a reverse logistics center, the waste pre-packaged e-liquids or bulk e-liquids must be managed as hazardous waste under §262.14
    - VSQGs can use optional provisions in Subpart P for pre-packaged e-liquids

FAQs

- How does this rule impact vape shops that are not VSQGs?
  - Pre-packaged e-liquids can be returned to a reverse logistics center provided there is a reasonable expectation they will be used/re-used or reclaimed. These would not be considered solid wastes or hazardous wastes.
  - If cannot be returned to a reverse logistics center, the waste pre-packaged e-liquids must be managed as non-creditable hazardous waste pharmaceuticals under Subpart P
  - Bulk e-liquids (any e-liquids not pre-packaged for retail sale) are not considered pharmaceuticals and remain subject to the P075 hazardous waste listing

Questions?

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